DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-68

July 11, 2001

Renee F. Goldstein, President
Salon Sciences Corporation
3299 S.W. 11th Avenue
Fort Lauderdale, Florida 33315

Dear Ms. Goldstein:

During an inspection of your facility on January 24-25 and 31, 2001, the Food and Drug Administration (FDA) investigator Susan M. Corrales found that your firm repacks, labels and distributes the product, "Fungi Septic Anti-Fungal Topical Liquid Therapy." The product is labeled to contain undecylenic acid as the active ingredient. Labeling for this product contains statements such as "High Potency Anti-Microbial Professional Formula," "Helps Keep Nails and Cuticles Clean, Conditioned and Healthy," "Reduces Moisture to Help Prevent Bacteria & Fungus Growth," "Professional Formula for Manicures, Pedicures and Artificial Nail Applications," "The Fungus Stops Here," "Anti-Fungal Topical Liquid Therapy," "Anti-Fungal First Aid For Fingers & Toes," and "Fungi Septic is a highly effective natural solution for the problem of stubborn fungus on fingers and toes. It provides a safe ... high potency ... anti-fungal treatment for topical use for manicures, pedicures or artificial nail application." In addition, under the section of "Directions," it includes "Clean the affected area ... Apply 2 coats of Fungi Septic to the cuticle and free-edge areas of fingers and toes. Also apply prior to any nail service or application." Further, this product is included under "Distribution Price List" section of the promotion booklet "Salon-Proven Nail Care for Professional Results ... At Home!"

The above statements represent and suggest that "Fungi Septic Anti-Fungal Topical Liquid Therapy" contains a powerful anti-fungal, anti-microbial and anti-bacterial agent that can be used with manicures, pedicures, or artificial nail applications. These statements and the name of the product, demonstrate the intended use of "Fungi Septic Anti-Fungal Topical Liquid Therapy" as a medication specific for treating nail infections, particularly fungus infections. Based on the product's intended uses, "Fungi Septic Anti-Fungal Topical Liquid Therapy" is a drug [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. It is subject to the final regulations contained in Title 21 of the Code of Federal Regulations (CFR) Part

310.545(a)(22)(iii), which state that there are no active ingredients recognized for over the counter use in treatment of fungal infections of the scalp and nails. Therefore, "Fungi Septic Anti-Fungal Topical Liquid Therapy" is a "new drug" [Section 201(p) of the Act]. A "new drug" may not be legally marketed in the United States without an approved New Drug Application as required by Section 505(a) of the Act.

This product is also misbranded under Section 502(a) of the Act because its labeling is false and misleading in that is suggests the product is safe and effective for its intended uses, when in fact, this has not been established. The product is further misbranded [Section 502(f)(1) of the Act] because its labeling does not bear adequate directions for its intended uses. It is not exempt from this requirement under 21 CFR 201.115 since it is a new drug [Section 201(p) of the Act] and no approval of an application filed is effective for the drug [Section 505(b)]. The product is further misbranded [Section 502(o) of the Act] because the product was manufactured in an establishment not duly registered [Section 510(b)] and it has not been drug listed as required [Section 510(j)].

The inspection further revealed that this drug is also adulterated within the meaning of Section 501(a)(2)(B) of the Act in that it is a drug product and the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs specified in Title 21, Code of Federal Regulations (CFR), Part 211, as follows:

Failure to perform finished product testing or, in lieu of such testing, obtain a Certificate of Analysis from the contract manufacturer. Where a Certificate of Analysis is received, no identity test is performed, nor is the reliability of the contract manufacturer's analysis established by appropriate validation;

An on-going, well controlled stability program has not been established, nor have stability studies been performed on products;

Packaged products lack expiration dates and they are not exempt from this requirement since appropriate data demonstrating stability of products over a three year period is lacking;

Failure to maintain adequate batch records for repackaged and labeled products;

Failure to establish written procedures for equipment cleaning, stability testing, packaging and labeling, distribution or complaint handling;

Failure to establish a control system for the receipt, testing and approval of the bulk products as well as drug containers and closures; and,

Failure to establish or implement an adequate label control system.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It remains your responsibility to ensure adherence to all requirements of the Act and regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations in the future. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Martin E. Katz, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

Kendall W. Storter

for Emma R. Singleton
Director, Florida District